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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/880,748	06/15/2001	Steven M. Ruben	PF523P1	5654

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EXAMINER	
DUFFY, PATRICIA ANN	

ART UNIT	PAPER NUMBER
1645	

DATE MAILED: 09/14/2004

11

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/880,748	Applicant(s) RUBEN ET AL.	
	Examiner Patricia A. Duffy	Art Unit 1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *07 July 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *75,79,81,82,87-89 and 97-145* is/are pending in the application.

4a) Of the above claim(s) *75,79 and 87-89* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *81, 82, 97-145* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *see attached*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

The amendment and response filed July 7, 2003 have been entered into the record. Claims 75, 79, 81, 82, 87-89 and 97-145 are pending.

Priority

Applicant's claim for domestic priority under 35 U.S.C. 119(e) is acknowledged.

Drawings

The drawings in this application have been approved by the Draftsperson.

Specification

The lengthy specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.

The disclosure is objected to because it contains an embedded hyperlink and/or other form of browser-executable code. Applicant is required to delete the embedded hyperlink and/or other form of browser-executable code. See MPEP § 608.01.

The use of the trademarks ATCC™ and BlyS™ have been noted in this application. It should be capitalized wherever it appears and be accompanied by the generic terminology.

Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

Information Disclosure Statement

The information disclosure statements filed July 7, 2003 and December 5, 2003 have been considered. Initialed copies are enclosed.

Election/Restrictions

Applicant's election with traverse of the antibodies in the reply filed on July 7, 2003 is acknowledged. The traversal is on the ground(s) that the treatment of antibodies is improper in view of the amended claims and that all Groups should be examined together because a search for the antibodies would reveal art on the other Groups of inventions. This is not found fully persuasive. The restriction/election requirement over the species of antibodies as set forth in the restriction requirement of record is withdrawn in view of the amendment to the claims. Claim 97 is a linking claim for all the antibody claims. Further, the recited types of antibodies, heavy or light chains are conventional and obvious variants of each other for antibody engineering purposes and each of which can be used for detection of human BlyS™ (SEQ ID NO:3228 and/or 3229). Applicants argue that the search for antibodies will reveal art on the other groups and therefore the groups should be properly examined together. This is not persuasive, the products are distinct as claimed and the products can be used in multiple methods and as such are distinct as claimedThe term "distinct" is defined to mean that two or more subjects as disclosed are related, for example, as product and method of use, etc., but are capable of separate manufacture, use or sale as claimed, and are patentable over each other (see MPEP 802.01). In the instant situation, the inventions of Groups are drawn to distinct inventions which are related as separate products capable of separate manufacture, use or sale as described in the previous Office Action. Restrictions between the inventions is deemed to be proper for the reasons previously set forth. In regard to burden of search and examination, MPEP 803 states that a burden can be shown if the examiner shows either separate classification, different field of search or separate status in the art. In the instant case a burden has been established in showing that the inventions of Groups are

classified separately necessitating different searches of issued U.S. Patents. However, classification of subject matter is merely one indication of the burdensome nature of search. The literature search, particularly relevant in this art, is not co-extensive, because, for example, the methods require search of steps and outcomes that are not required for the product per se. The methods as claimed are not related because they have different method steps, have different goals and different final outcomes. Additionally, it is submitted that the inventions of the Groups have acquired a separate status in the art methods of detection are not related to methods of treatment. Clearly different searches and issues are involved in the search and examination of each Group.

For these reasons the restriction requirement is deemed to be proper and is therefore made FINAL.

Claims drawn to nucleic acids (75, 79 and 87-89) are withdrawn from consideration. election with traverse in the response of July 7, 2003 is acknowledged.

Double Patenting

Claims 81, 82 and 97-145 of this application conflict with claims 3, 4, 5, 6, 7, 17-19, 20, 21, 33 and 35 of Application No. 10/293,418. 37 CFR 1.78(b) provides that when two or more applications filed by the same applicant contain conflicting claims, elimination of such claims from all but one application may be required in the absence of good and sufficient reason for their retention during pendency in more than one application. Applicant is required to either cancel the conflicting claims from all but one application or maintain a clear line of demarcation between the applications. See MPEP § 822.

A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus,

the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

Claim 144 and 145 are provisionally rejected under 35 U.S.C. 101 as claiming the same invention as that of claims 33 and 35 of copending Application No. 10/293,418. This is a provisional double patenting rejection since the conflicting claims have not in fact been patented.

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 97-101, 119-143 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 33 and 35 of copending Application No. 10/293,418. Although the conflicting claims are not identical, they are not patentably distinct from each other because the scFV species of SEQ ID NO:2 and 327 anticipates the instantly claimed genus and enginering the scFV CDR's inot other constant framework regions is prima facie obvious and the antigen binding fragments of any antibody are prima facie obvious over the intact molecule because the fragments provide for decreased cross-reactivity in detection assays.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 81, 82 and dependent claims 102, 104, 105, 106, 107, 108, 111, 112, 113, 114, 115, 116 and 117 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter.

The claimed invention is drawn to a protein product of nature. Products of nature are not patentable because they do not reflect the "hand of man" in the production of the product or manufacturing process. Diamond v. Chakrabarty, 206 USPQ 193 (1980). Additionally, purity of naturally occurring product does not necessarily impart patentability. Ex parte Siddiqui 156 USPQ 426 (1966). However when purity results in new utility, patentability is considered. Merck Co. V. Chase Chemical Co. 273 F. Supp 68 (1967). See also American Wood v. Fiber Disintergrating Co., 90 US 566 (1974);American

Fruit Growers v. Brogdex Co. 283 US 1 (1931); Funk Brothers Seed Co. V. Kalo Innoculant Co. 33 US 127 (1948). Filing of arguments and evidence of a new utility imparted by the increased purity of the claimed invention *and amendment to the claims to recite the essential purity* of the claimed products is suggested to obviate this rejection. For example, "An isolated or purified antibody...".

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:
The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The following is a quotation of the second paragraph of 35 U.S.C. 112:
The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 81, 82, 102-118 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a written description rejection.

The claims are drawn to an antibody that competitively inhibits the binding of the I006D08 antibody produced by the cell ine having ATCC deposit number PTA-3239 to BlyS

wherien said antibody competitively inhibits said binding more than the I006D08 antibody competitively inhibits itself or an antibody that competitively inhibits the binding of the I116A01 antibody produced by the cell ine having ATCC deposit number PTA-3240 to BlyS wherien said antibody competitively inhibits said binding more than the I116A01 antibody competitively inhibits itself.

The teachings of the specificaiton are limited to the I006D08 and I116A01 antibodies produced by the claimed cell lines and a plethora of other scFv antibodies that bind BlyS comprising residues 134-285 as set forth in SEQ ID No: 3228. The specification does not teach the epitope that each of the antibodies bind nor does not teach the binding affinity or competitive nature of any of the antibodies of Table 1 as compared to either the I006D08 and I116A01 antibodies or even if they compete for binding the same epitope on BlyS™ comprising resudues 134-285 as set forth in SEQ ID No: 3228. Dependent claims futher limit the antibody binding to multimers, functional limiations of inhbition activity and receptor binding. The specificaiton also does not teach a genus of antibodies that have the claimed competitive inhibitory properties as binding to multimers, homomeric or heteromeric. One skilled in the art can not envision the genus of antibodies with the claimed function because not a single antibody meeting the functional limiation is described in the specificaiton as having that property at the time of filing the instant application. The term BLyS™ encompasses a genus of "B lymphocyte stimulting proteins" and the specification teaches binding to human and murine or human alone and not the genus of BLyS™. The term BlyS™ is seen to encompass any other proteins with the same function. The specification does not describe BlyS™ genus-specific antibodies. In other words, the specification does not describe any antibodies that bind the genus of functional equivalents *per se* as is istantly claimed. The specification also lacks written description of any antibody binding to multimers of BLyS™ whether they are homomers of BlyS™ variants or heteromers of BlyS™ and other TNF homologs such as APRIL. The specificaiton does not teach the ability of any disclosed antibody to bind multimers of

BlyS™ that are not multimers of BlyS™ comprising resudues 134-285 as set forth in SEQ ID No: 3228. The specifictation does not teach the assembly of murine and human BlyS™ monomers into a functional dimer or trimer or any variant of BlyS™ or TNF homolog such as April. Further, even if these multimers can be formed, there is no description of any of the antibodies in Table 1 binding to these heteromeric forms of BlyS™ and it is unclear how assembly of multimers affects binding of any of the antibodies of Table 1 to BLyS™. The specification does not teach that any of the antibodies of Table 1 have the recited functional property. For the foregoing reasons, the specification at the time of filing does not allow the skilled artisan to envision any genus of antibodies with the functional property of "wherien said antibody competitively inhibits said binding more than the I008D06 or I116A01 antibody competitively inhibits itself" or binding to the genus of BlyS™ polypeptides or multimeric forms there of that are not multimers of human BlyS™ comprising resudues 134-285 as set forth in SEQ ID No: 3228.

Claims 97-101 and 119-143 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a written description rejection.

The claims are drawn to antibodies that have a requistie percent identity as compared with VH and VL domains of SEQ ID NO:327 and immunospecifically bind to BLyS™. The teachings of the specification provide for a wide variety of scFv antibodies that immunospecifically bind to BLyS™ comprising resudues 134-285 as set forth in SEQ ID No: 3228 (i.e. the soluble human or membrane human forms). The term BLyS™ encompasses a genus of "B lymphocyte stimulting proteins" and the specification teaches binding to human and in certain limited cases murine or human alone, and not the genus of BLyS™ of functional equivalents, the rat or the monkey variants. The term BlyS™ is seen

to encompass any other proteins with the same function. The specification does not describe BLyS™ genus-specific antibodies. In other words, the specification does not describe any antibodies that bind the genus of functional equivalents *per se* as is istantly claimed. Further, with respect to binding multimers. The term multimers includes homomers of different species of BlyS™ and heteromers with different TNF homologs such as APRIL. The specificaiton does not teach the ability of any disclosed antibody to bind multimers of BlyS™ that are not multimers of human BlyS™ comprising resudues 134-285 as set forth in SEQ ID No: 3228. The specifictation does not teach the assembly of murine and human BlyS™ monomers into a functional dimer or trimer or any variant of BlyS™ or TNF homolog such as April. Further, even if these multimers can be formed, there is no description of any of the antibodies in Table 1 binding to these heteromeric forms of BlyS™ and it is unclear how assembly of multimers affects binding of any of the antibodies of Table 1 to BLyS™ comprising resudues 134-285 as set forth in SEQ ID No: 3228. The specification does not teach that any of the antibodies of Table 1 have the recited functional property. For the foregoing reasons, the specification at the time of filing does not allow the skilled artisan to envision any genus of antibodies with the functional property of binding multimers or the genus of BlyS™ polypeptides as instantly claimed.

Claim 99 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a new matter rejection.

The specificaiton at [0243-0244] teach that the percent identity is intended to encompass the percent as it relates to any "one of" the domains as listed in Table 1. Table 1 lists the amino acid sequences of VL, VLCDR1, VLCDR2, VLCDR3, VH, VHCDR1, VHCDR2,

and VHCDR3. Consequently, the reciation of "in one or more of the CDR's" is new matter as it realates to percent identity because the cited passage is directed to "one of" the domains of Table 1 and not multiples thereof as is now claimed.

Claims 144 and 145 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The specification lacks complete deposit information for the deposit of the cell lines from which the antibodies are purfied. Because it is not clear that cell lines possessing the properties of the cell lines from which the claimed antibodies are isolated publicly available or can be reproducibly isolated from nature without undue experimentation and because the claims require requires the use of the particularly claimed cell line to isolate the antibody, a suitable deposit for patent purposes is required. Without a publicly available deposit of the above cell line, one of ordinary skill in the art could not be assured of the ability to practice the invention as claimed. Exact replication of the cell line is an unpredictable event. Applicant's referral to the deposit of the cell lines producing the claimed antibodies on page 144 of the specification is an insufficient assurance that all required deposits have been made and all the conditions of 37 CFR §1.801-1.809 have been met. Since the deposit has been made under the provisions of the Budapest Treaty, filing of an affidavit or declaration by applicant or assignees or a statement by an attorney of record who has authority and control over the conditions of deposit over his or her signature and registration number stating that all restrictions upon public access to the deposit will be irrevocably removed upon the grant of a patent on this application. This requirement is necessary when deposits are made under the provisions of the Budapest Treaty as the Treaty leaves this specific matter to the discretion of each State.

Claims 81, 82, 97-145 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The term BLyS™ is an active trademark. The use of trademarks in the claim is *prima facie* indefinite because any chemical represented is not inexorably tied to the trademark. That is the trademark can be used to represent different materials. As such, the claim is indefinite because it does not represent any chemical structure per se. It should be capitalized wherever it appears and be accompanied by the generic terminology of the structure of molecule which it represents.

As to claims 81, 82, 144 and 145, the word ATCC™ is also an active trademark. As such, it should be recognized as such. It should be capitalized wherever it appears and be accompanied by the generic terminology.

As to claims 81, and 82 and evey claim dependent thereon, the claim recites an antibody that competitively inhibits the biding of the I006D08 antibody produced by the cell line having ATCC™ to BLyS™ wherein said antibody competitively inhibits said binding more than the I006D08 antibody competitively inhibits itself. This language is confusing because any antibody will competitively inhibit itself 100%. Therefore, it is unclear how any antibody can competitively inhibit more than 100%. It is unclear how this "competitive inhibition" is measured and how one can measure more than 100%. Applicants should point to the specification by page and line number where competitive inhibition is defined in such a manner that would define the metes and bounds of inhibiting more than itself would be clearly and unambigously understood.

Claim Rejections - 35 USC § 102 and 103

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 81, 82, 102, 107, 111-118 are rejected under 35 U.S.C. 102(b) as being clearly anticipated byTribouley et al, Biol Chem. 380:1443-1447, December 1999, of record in PTOL-1449).

Tribouley et al teach that the TNFSR20 polypeptide described therein is the same factor described by Moore et al, 1999 and Schneider et al, 1999 which are BlyS and BAFF respectively (see page 1447, column 1 and referenceces cited in column 2). Tribouley et al teach a rabbit polyclonal antibody (D2710) was raised against a peptide derived from the human protien sequence spanning amino acid 234-248, which is a region highly conserved between the human and mouse protiens and differs by only 4 amino acids. Since the antibody of the art is polyclonal with multiple specifities it would inherently "compete more" than the claimed scFv for BLyS™/TNFSR20 due to steric inibition of binding of a multiple antibodies as compared with a single antibody. Since the epitope that the scFv's produced by the cell lines is not taught by the application, and since the Office does not have the facilities for examining and comparing applicant's protein with the protein of the prior art, the burden is on applicant to show a novel or unobvious difference between the claimed product and the product of the prior art (i.e., that the antibody of the prior art does not possess the functional characteristics of the claimed antibody). See In re Best, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and In re Fitzgerald et al., 205 USPQ 594.

Claims 81, 82, 102, 107, 111-118 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Mukhopadhyay et al (The Journal of Biological Chemistry, 274(23):15978-15981, June 4, 1999; of record in PTOL-1449).

The examiner take official notice that the polypeptides acronyms BlyS™ , VAF, TALL-1, THANK and zTNF4 are all the identical polypeptide but are known by different names in the prior art. Mukhopadhyay et al teach a polyclonal rabbit anti-THANK antibody. The polyclonal antibody immunospecifically bind THANK and inhibit THANK-mediated NF-κB activation in U937 cells (see page 15980, column 1, Figure 2 and paragraph bridging columns 1-2). Since the antibody of the art is polyclonal with multiple specifities it would inherently "compete more" than the claimed scFv for BLyS™/THANK due to steric inibition of binding of a single antibody. Further, because Mukhopadhyay et al teach that the polyclonal antibody neutralizes activation of cell in in vitro, it necessarily follows that the polyclonal antibody binding inhibits all functions because it binds across the entire molecule. Since the Office does not have the facilities for examining and comparing applicant's protein with the protein of the prior art, the burden is on applicant to show a novel or unobvious difference between the claimed product and the product of the prior art (i.e., that the antibody of the prior art does not possess the functional characteristics of the claimed antibody). See In re Best, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and In re Fitzgerald et al., 205 USPQ 594.

Status of the Claims

All claims stand rejected.

Allowable Subject Matter

The following claim represents the broadest allowable claim at this point in prosecution.

Claim A. An isolated antibody that immunospecifically binds a BLyS™ polypeptide comprising resudues 134-285 as set forth in SEQ ID No: 3228, wherein said antibody comprises a first amino acid sequence at least 85% identical to amino acid residues 1-123 as set forth in SEQ ID NO:327 and a second amino acid sequence at least 85% identical to amino acid residues 139-249 as set forth in SEQ ID NO:327.

Claims 98, 100, 102, 119, 127, 130-143 as dependent thereform.

Conclusion

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Patricia A. Duffy whose telephone number is 571-272-0855. The examiner can normally be reached on M-F 6:30 pm - 3:00 pm. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith can be reached on 571-272-0864.

The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Patricia A. Duffy, Ph.D.

Primary Examiner

Art Unit 1645